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An Institutional Examination of the Implications of the Unitary Patent Package for the Morality Provisions: A Fragmented Future Too Far?¹

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Abstract

This article examines the institutional changes created by the unitary patent package (UPP), including the unified patent court (UPCt), in the European patent system. It focuses specifically on the implications of these changes for the morality provisions for biotech inventions: contained in Art 53(a) EPC and Art 6 Biotechnology Directive 98/44EC. These provisions were chosen as a site of investigation because of the overlap of substantive EU and EPC laws involved. Furthermore, despite the identical wording of these provisions in the EPC and Directive, the open-textured nature of these morality provisions requires interpretation by the adjudicative bodies in each institutional framework. Hence, institutional influences on adjudicative bodies are heightened. Accordingly, these provisions provide an ideal site to examine the significance of the addition of another adjudicative body, the UPCt to the European patent system.

The article examines the implications of having adjudicative bodies operating in differing institutional frameworks in contexts where States have overlapping obligations to international treaties. It argues that the UPCt is not institutionally configured to apply these provisions in the same manner as the generalist CJEU and demonstrates that the UPCt's openness to refer questions to the CJEU is crucial to ensuring the UPP does not become blinkered to broader issues. Moreover, it argues that the unitary nature of the European Patent with unitary effect (EPUE) is problematic because it fails to accommodate national divergence on the morality provisions and it is unclear whether morality is to be judged at a national, EPC or EU level. A mechanism for maintaining national divergence in this context is proposed.

Keywords: Unified Patent Court; Morality Provisions; Institutional.

Introduction

The recently adopted unitary patent package (UPP) introduces the European patent with unitary effect (EPUE) which will be available in all participating EU States. This will operate in parallel to, and will not replace, the classical European patent (EP) route which provides a single patent application route for applicants seeking patents in two or more European Patent Convention (EPC) States – currently 38 Contracting States including all EU States. Under the classical EP route, applicants apply to the European Patent Office (EPO) for a patent and if granted, the applicant receives a bundle of national patents in the EPC States designated in the application. However, the post-grant life of these patents lies primarily under the individual jurisdiction of each national State. In contrast to this, the EPUE's post-grant life will be governed by the newly created Unified Patent Court (UPCt) and it will have unitary effect² i.e. equal protection in all participating States. The UPP system significantly alters

¹ The author would like to thank Professor Graeme Laurie, Mr Gerard Porter and Professor TT Arvind for their valuable comments on earlier drafts of this work. All errors and omissions remain the author's own.

² Recital 7 of Regulation 1257/2012.

the institutional framework in the European patent system³ by increasing the number of supranational adjudicative bodies operating in this system and by changing the types of patents available.

Moreover, the UPP increases participating States' overlapping obligations to differing international treaties/agreements. This exacerbates the potential for tensions which would result if conflicting interpretations were given by the supranational adjudicative bodies charged with the interpretation of relevant patent law instruments, i.e. the EPO, Court of Justice of the European Union (CJEU) and UPCt. This will be particularly significant in areas where there is legislative overlap between EU instruments and the European Patent Convention (EPC) such as for patents on biotechnological inventions. In this context, the EU's Biotechnology Directive⁴ currently operates alongside the EPC and both legislative instruments are binding on EU States. Whilst there has been convergence at a legislative level between the European Patent Organisation (EPOrg) and the EU as the Biotechnology Directive was adopted as a supplementary means of interpretation by the EPC for patents on biotechnological inventions.⁵ However, it is questionable whether such convergence is always mirrored at a judicial/quasi-judicial level. Indeed, the EPOrg is not party to the Biotechnology Directive or the EU, and equally the EU is not party to the EPC. Instead, the convergence evident is entirely voluntary in nature;⁶ neither the EU nor the EPOrg is legally bound to follow the other's approach.⁷ This leaves open the possibility for diverging interpretations at a supranational level as questions relating to the patentability of biotechnological inventions can be decided by the EPO - for instance in Opposition Division proceedings; and also by the CJEU if a preliminary referral is made by a national court.

If these supranational bodies take differing approaches, this would be problematic given that EU States are party to both the EPC and Biotechnology Directive. It would also give rise to practical issues as the EPO is the patent granting body for EU States in the classical EP system. The UPP will exacerbate such issues as it increases the institutional complexity and fragmentation at a *supranational* level within the European patent system. Put simply, it further fragments the patent landscape into UPP States, EU States not party to the UPP, and non-EU States party to the EPC alone. It also adds a third supranational adjudicative forum, the UPCt, to this system which will operate alongside the Boards of the EPO and CJEU. Moreover, although there are links between the UPCt and CJEU (discussed in section 3 below), the UPCt is not bound to follow the approach of the EPO or *vice versa*, instead, these bodies operate separately from each other at post-grant stage.

This article examines the institutional changes to which the UPP gives rise in this area of legislative overlap between the EU/EPOrg. In doing so, it focuses specifically on the morality provisions in the European patent system which are set out in Art. 53(a) of the EPC and in Art. 6 of the Biotechnology Directive. The general

³'European' is used to refer to the system operating under the European Patent Convention (EPC), an intergovernmental treaty adopted in 1973 which has 38 participating States including all European Union (EU) States and 10 non-EU States.

⁴ Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions.

⁵ Rule 26, Implementing Regulations to the EPC.

⁶ Waelde et al, 2014, para 10.27; Bakardijieva Engelbrekt, 2009.

⁷ Wisconsin Alumni Research Foundation (WARF) (G002/06), Decision of the Enlarged Board of Appeal of 25 November 2008, para 7. However, it is conceded that politically these bodies are likely to seek to follow a similar approach given the EPO's role as granted body for all classical EP patents.

morality provision in both instruments provides that inventions will be unpatentable if their commercial exploitation would be contrary to “ordre public” or morality. Furthermore, Art. 6(2) of the Directive provides a non-exhaustive list of four categories of inventions which are specifically excluded under these provisions, namely: “(a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.” These four listed exclusions were also subsequently incorporated in the EPC framework.⁸ These provisions have been chosen as a site of investigation because despite their identical wording in the EPC and the Directive, the open-textured nature of the general morality provision requires interpretation by the adjudicative bodies applying them in each institutional framework which defines the parameters of these provisions. Thus, it will be argued that institutional influences on adjudicative bodies are heightened in this context and as a result these provisions provide an ideal site to examine the significance of the addition of another adjudicative body, the UPCt to the European patent system.

Importantly, the problem which arises in this context is not the risk of divergence or differing interpretations *per se*; already in the classical EP system Contracting States have post-grant jurisdiction which accommodates divergence amongst national States on the application of the morality provisions. Instead, the difficulty which is exacerbated by the UPP is that the morality provisions will now be interpreted by three *supranational* adjudicative bodies, which this article argues are not institutionally configured to apply these provisions in the same manner. If these bodies give unilateral or unitary interpretations of these provisions at a supranational level which deny patents on the basis of the morality provisions in all of their Contracting States, this would be problematic because many States have overlapping obligations under the Biotechnology Directive, EPC and the Agreement on the Unified Patent Court (AUPC).. Moreover, in this particular context, another issue is that States are generally afforded a margin of appreciation on moral issues. As will be examined, this approach has been expressly confirmed by the CJEU for the general morality provisions under the Biotechnology Directive⁹ and this mirrors the jurisprudence of the ECtHR which provides deference to States on sensitive moral issues where there is no consensus.¹⁰ However, the ‘unitary’ nature of the EPUE does not provide space for such national divergence – EPUEs must have equal protection in all States. This article argues that this is contrary to existing EU obligations to respect national traditions and that this aspect of the EPUE must be reconsidered to provide deference for States on the interpretation of the morality provisions. A proposed mechanism to achieve this is set out in part 4.

In taking this focus, the analysis makes an original contribution for three reasons. Firstly, despite extensive discussions on the UPP,¹¹ there has been very limited consideration of the relevance of this institutional change for the morality provisions.¹² This article fills this gap. In doing so, as noted, it argues that the introduction of the UPP in its current form is problematic for the morality provisions for two main reasons. Firstly, the UPP increases

⁸ Rule 28 of the Implementing Regulations to the EPC.

⁹ Case 377/98 *Netherlands v European Parliament and Council* [2001] ECR I-07079.

¹⁰ Yourow 1996, p 13.

¹¹ Including: Kaesling 2013; Zawadska 2014; Hilty, Jaeger, Lamping, and Ullrich 2012; West, Kusumakar, Powell 2013; Kaisi 2014; Aerts 2014b; Ohly and Pila 2013; Pila and Wadlow 2014.

¹² This is alluded to but not examined in detail in: Petersen, Riis and Schovsbo 2015; Kaisi 2014; Aerts 2014a.

the institutional *supranational* overlaps within the current system thereby exacerbating existing institutional tensions by increasing the avenues for conflicting interpretations at a supranational level. This analysis resonates with and contributes to general discussions in international law on conflicting obligations under differing legal instruments and how these can be reconciled;¹³ and to debates in relation to fragmentation of international law, albeit from a patent perspective. Secondly, the article argues that although harmonisation in the patent field is desirable in many contexts, the morality provisions are a peculiar case which require there to be leeway for States to differ in moral approaches. This leeway is currently provided under the classical EP route as post-grant issues are vested in the national State which provides a means to allow a margin of discretion to States on moral issues. However, the ‘unitary’ nature of the EPUE expressly excludes divergence amongst States. This approach fails to safeguard protection for State’s moral traditions e.g. should a case arise where one State wishes to deny a patent based on moral concerns where other States would be willing to uphold this. It will be argued that this is contrary to the EU’s obligations to respect national identity, and to previous case law of the CJEU¹⁴ confirming a margin of discretion for States on the general morality provisions. This article argues that mechanisms to facilitate deference for national States on the general morality provisions must be provided for. This in turn contributes to discussions of the need for a margin of appreciation for sensitive moral/ethical issues under the ECHR, and the balance that has to be maintained between allowing scope for strict international standards/principles whilst maintaining deference for States where necessary.

Secondly, this article is the first to apply institutional theory in this way to examine the morality provisions in the patent system. It uses understandings from institutional theory to formulate a novel template for examining the main institutional influences on adjudication in this system, detailed in part three. It then applies this to the proposed UPP system. This template although used here to analyse the morality provisions, is transplantable to other contexts and is useful for examining all instances where States have overlapping obligations to international instruments eg. States obligations to UN and EU treaties.

Thirdly, using this institutional approach the article argues that account must be taken of how substantive laws are likely to be interpreted in differing ways depending on the institutional contexts evident. This has important practical ramifications as it means that when normative proposals for legislative reform are made it is crucial to consider how these reforms are likely to be interpreted by supranational adjudicative bodies situated in differing institutional frameworks. Moreover, although this article is directed at the morality provisions this analysis is also relevant for other open-textured provisions/concepts used in the patent system such as the patentability criteria as it argues that all open-textured principles are heavily shaped by the institutional framework within which they are interpreted which define the contours of such provisions.

The article is structured as follows: Part one commences by giving an overview of the UPP setting the foundations for the analysis. Part two then examines the increasing fragmentation at a supranational level which the UPP gives rise to and the consequences of this should conflicting interpretations arise. Following this, Part three uses

¹³ Similar debates have occurred in context of: Case C-402/05 P and C-415/05 P. *Kadi and Al Barakaat International Foundation v. Council and Commission* [2008] ECR I-6351, eg, see Besson 2009; de Burca 2010.

¹⁴ Case C-377/98 *Netherlands v European Parliament and Council*, Judgment of the Court, 9 October, 2001.

institutional theory to highlight why this is particularly problematic in the context of the morality provisions. It argues that institutional influences are heightened in the interpretation of the morality provisions because: (1) the open-textured nature of these provisions, and (2) the malleable nature of the concept of morality. It sets out a novel template which maps the main categories of constraining and predictive institutional influences which exist and may influence adjudicative bodies such as the CJEU/EPO/UPCt. This template is then applied to the UPCt. The article argues that given the UPCt's peculiar institutional characteristics it will have a differing underlying interpretative approach to these provisions in comparison to bodies such as the CJEU thereby increasing the potential for differing supranational interpretations of these provisions, unless it engages closely with the CJEU in the interpretation of such provisions. Part four then examines the unitary nature of the EPUE arguing that this will be problematic for the morality provisions because of: (1) the lack of scope in the current system to maintain discretion for States to respect differing moral traditions; and (2) it is unclear whether morality in this context will be judged at a national, UPP participating State, EU or EPC State level.

Finally, part five concludes by reiterating the significant influence that institutional frameworks have on adjudicative bodies which accordingly must be central to discussions on the formation of new courts such as the UPP, given the impact of this on the interpretation of substantive patent law, and particularly, on open-textured concepts. It argues that although there has been reluctance to involve the generalist CJEU in the UPP system, however, areas such as the morality provisions where broader social and human rights issues are at stake require oversight from the CJEU as specialist courts may become blinkered from broader considerations. Developing closer links with the CJEU through referrals from the UPCt to the CJEU where needed on such areas would help to minimise this risk and would allow the system to offer a balance between specialist and generalist expertise depending on the context which arises. Furthermore it argues that the UPP system must provide a means to maintain divergence for national States on the morality provisions - a form of moral subsidiarity - which the EPUE in its current form does not provide.

1. Overview of the Unitary Patent Package

Proposals to establish a unitary patent for Europe span the last fifty years,¹⁵ and on the 17th December 2012 the Council for the EU signed two regulations¹⁶ paving the way for the EPUE in participating EU States. Originally, the unitary patent plans included all EPC States¹⁷ but following unsuccessful initiatives,¹⁸ plans commenced for the adoption of a unitary patent available only in EU States. However, these plans also ran into difficulties in light of disagreements relating to translation arrangements making agreement impossible.¹⁹ Consequently, an enhanced

¹⁵ Plomer 2015; McDonagh 2014, p 7. See also: Mahne 2012; Jacob 2004; Luginbuehl 2011; Brinkhof and Ohly 2013.

¹⁶ Regulation 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection, OJ L 361/1 of 31.12.2012 (Regulation 1257/2012); Council Regulation 1260/2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to applicable translation arrangements (Regulation 1260/2012).

¹⁷ The most recent proposal planned a Court within the EU system with jurisdiction for both EU and non-EU EPC Contracting States. This was deemed incompatible with EU law: Opinion 1/09 [2011] ECR I-1137.

¹⁸ See, Brinkhof, and Ohly 2013, p 200; Kaisi 2013, p 173.

¹⁹ Council Decision of 10 March 2011 authorising enhanced cooperation in the area of the creation of unitary patent protection (2011/167/EU).

cooperation scheme was adopted by the EU States who wished to participate in the UPP.²⁰ The participating States subsequently changed. Italy initially opted out of the scheme but following unsuccessful challenges to the UPP,²¹ Italy sent notification in July 2015 confirming its intention to join.²² In contrast, Poland initially agreed to the system but declined to sign the Agreement on the Unified Patent Court (AUPC). Thus, 25 EU States are now party to the agreement.²³ There are also indications that Croatia which joined the EU in July 2013 may join the UPP.²⁴ Importantly, the UPP is open to any EU State²⁵ but not to non-EU States, e.g. the 10 EPC States who are not EU States. Consequently, the UK's 'Brexit' referendum on 23rd June 2016 which declared a vote to leave the EU means that when the UK leaves the EU, it will no longer be able to participate in the UPP.²⁶ A solution may be found to this, for instance, there has been discussion of UK ratification of the UPP prior to leaving the EU.²⁷ However, at the time of writing, it is unclear how likely this is and even if it were legally possible, the issues which will arise after the UK leaves the EU for the UPP would need to be addressed e.g. how the CJEU's role in the UPP would operate if the UK were in the UPP but ceased to be an EU State. What is clear, is that, from an institutional perspective, the UPP does not create full harmonisation in the European patent system with – currently- three EU States remaining outside the UPP and 10 other EPC States which cannot join the UPP.

Moreover, the UPP retains existing institutional links with the EPO as nothing changes from the classical EP system at the grant stage. Applicants apply to the EPO under the same process they would for a classical EP designating States in which they desire a patent.²⁸ Once granted, if the applicant wants an EPUE, they must file a request to the EPO for unitary effect in the participating EU States within one month of the publication of the patent grant in the European Patent Bulletin.²⁹ Thus, despite the fact that it is an EU initiative, at the grant stage the system is dependent or grafted onto the EPO's decision to grant a patent bundle.³⁰ This dependence on the EPO system and the fact that the compliance of an invention with patentability requirements is assessed in the first instance by the EPO reinforces existing institutional overlaps.

However, it is at post-grant stage that the main changes brought about by the UPP are evident, as the EPUE has unitary post-grant effect in participating States.³¹ In order to achieve this post-grant effect, the EPUE is supplemented by the UPCt whose establishment is set out in the AUPC.³² However, the UPCt is not an EU court

²⁰ Regulation 1257/2012; For an overview of the process leading to the adoption of the current model, see Pistoia 2014.

²¹ Spain and Italy challenged the enhanced cooperation process in Joined Cases C-274/11 and C-295/11 [2013] 3 CMLR 24.

²² Council of the European Union, General Secretariat of the Council 'Notification by Italy of its intention to participate in the enhanced cooperation in the area of the creation of unitary patent protection and in the enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements' (7 July 2015) <http://data.consilium.europa.eu/doc/document/ST-10621-2015-INIT/en/pdf> Accessed 5 August 2016.

²³ All except: Spain, Poland and Croatia.

²⁴ Battistelli 2013.

²⁵ Select Committee of the Unified Patent Court 2014, p 7.

²⁶ See, Johnson 2015.

²⁷ Kluwer UPC News Blogger 2016.

²⁸ For a discussion of the role of the EPO as the granting body see: Ullrich 2012b.

²⁹ Recital 18, Regulation 1257/2012.

³⁰ Jaeger 2014, p 18.

³¹ Recital 5, Regulation 1257/2012.

³² Council Agreement on a Unified Patent Court (2013/C 175/01).

but rather has been designed akin to a national court of the Member States (MSs), and is modelled on the Benelux court.³³ Nonetheless, EU law has primacy in decisions of this court.³⁴ Thus, as will be discussed, unlike the Boards of the EPO, the UPCt is bound by EU law and can refer questions to the CJEU. However, the UPP is a specialist court dealing only with patent issues with members drawn from within the pool of patent practitioners, therefore in form it has more resemblance to the Boards of the EPO than the CJEU. These factors will impact upon how it may interpret the morality provisions and are examined in part three.

In terms of the timeline for its implementation, the UPP will operate from the date of the entry into force of the AUPC.³⁵ This will come into effect four months after the AUPC has been ratified by thirteen Contracting States, provided these include the three States which have the highest number of EPs in force in the preceding year, currently, Germany, the UK and France.³⁶ However, the UK's vote to leave the EU is likely to delay the implementation of the UPP as until it leaves the EU it will still be considered a formal member of the EU and its ratification will be required³⁷ as a State with one of the highest number of patents in force. At the time of writing, the AUPC has been ratified by ten countries, not including Germany or the UK.³⁸ Thus, it is likely to be 2018 or later before it comes into place, with much depending on the UK's withdrawal from the EU. However, as the UPP becomes closer to reality, far from being welcomed, the package and compromises that have been necessary to bring it to this stage have been criticised extensively.³⁹ Nonetheless, it appears to be going ahead despite such concerns, and when it takes effect, it will have significant implications for the morality provisions.

2. The Institutional Landscape under the UPP: Further Supranational Fragmentation in the Application of the Morality Provisions

The proposed UPP introduces a third supranational forum, the UPCt, and increasing layers to the already fragmented European patent system. In doing so, it changes the institutional framework within which the morality provisions are adjudicated upon, particularly at the post-grant stage where the changes create further possibilities for overlapping interpretations at a supranational level. This is demonstrated by analysing the pre and post grant stages of the planned UPP framework examined in part 2.1 and 2.2 below. This is followed in 2.3 by a critical analysis of the consequences of this deepening supranational fragmentation should conflicting interpretations arise.

2.1 Implications for the Morality Provisions at Pre-Grant Stage under the UPP

An EPUE is obtained in the same way as classical EPs: the EPO acts as granting body assessing patentability requirements. The EPO undertakes this role in spite of the fact that the EPUE will only be available in participating

³³ Brikhof, and Ohly 2013, p 211.

³⁴ Art. 20 AUPC.

³⁵ Art. 18(2) Regulation 1257/2012.

³⁶ Select Committee of the Unified Patent Court 2014, p 19.

³⁷ Baker 2016.

³⁸ This is correct at the time of writing 8th August 2016.

³⁹ This includes: Hilty, Jaeger, Lamping and Ullrich 2012; Ullrich 2012a; Jaeger 2012; Ullrich 2012b. See also, judicial challenges: Joined Cases C-274/11 and C-295/11 [2013] 3 CMLR 24; Case 146/13 *Kingdom of Spain v European Parliament and Council of the European Union*, Judgment of the Court 5th May, 2015.

EU States and that EU law has primacy within the UPP system. This raises questions as to the defensibility of the application of the morality provisions if, as will be argued in part 3, the decision-making bodies of the EPOrg and EU are not institutionally configured to interpret these provisions in the same manner.

Nonetheless, the EU Commission⁴⁰ has stressed that the Biotechnology Directive has been “fully integrated in the legal framework of the European Patent Organisation”⁴¹ and the patentability requirements for EPUEs are identical to classical EPs. However, despite the voluntary convergence between the EPOrg and EU at a legislative level, this article argues that the interpretation of the morality provisions at an adjudicative level is deeply bound to, if not contingent upon, the institutional frameworks within which decision-makers operate. Considered from this perspective, it would be impossible to fully integrate the interpretative practices of the CJEU into the EPO’s decision-making framework without fundamentally reconfiguring the institutional framework within the EPOrg. Thus, whilst it is accepted that the UPP does not change patentability criteria, there are already arguably distinctions between the EU and EPO adjudicative bodies’ interpretative approaches to the morality provisions which give rise to questions surrounding the defensibility of the application of the morality provisions, across and between the EPOrg/EU systems. Given that the UPP system retains the EPO as a granting body under the UPP these institutional issues remain. Indeed, given that the UPCT is in form more akin to the Boards of the EPO, arguably if anything it exacerbates such underlying issues, a point which is returned to in part three.

2.2 Implications for the Morality Provisions at Post-Grant Stage under the UPP

Turning to the post-grant stage, as noted, the EPUE is ancillary to and does not replace the classical EP or national patent scheme.⁴² Once adopted, the UPCT will have jurisdiction for all EPUEs, and following a transitional period, it will have jurisdiction for all classical EPs granted to participating States.⁴³ Therefore, once in force, four overlapping protections for patents will exist within the European patent system, namely: (1) a national patent granted by national EPC Contracting States; (2) an EPUE granted by the EPO with post-grant jurisdiction vested in the UPCT; (3) a classical EP granted by the EPO but with post-grant jurisdiction governed by the national States; and (4) an EP granted by the EPO valid in the AUPC Contracting States whose post-grant life will be governed by the UPCT.⁴⁴ These changes alter the adjudicative bodies charged with the interpretation of the morality provisions should a challenge arise on this basis at the post-grant stage through revocation actions,⁴⁵ and also reinforce institutional complexities for opposition proceedings.⁴⁶

2.2.1 Revocation Proceedings

Currently, revocation proceedings are dealt with by the national court for all classical EPs which after grant are refracted into a bundle of national patents. However, this will change under the UPP system, as the AUPC provides that EPUEs and all classical EPs validated in the Contracting States of the AUPC are under the jurisdiction of the

⁴⁰ EU Commission, Patent Reform Package 2012, question 20.

⁴¹ Ibid.

⁴² Regulation 1257/2012, recital 26.

⁴³ Art. 3 AUPC.

⁴⁴ Hilty, Jaeger, Lamping and Ullrich 2012, p 1.

⁴⁵ Art. 138(1)(a) EPC.

⁴⁶ Art. 99-100 EPC.

UPCt.⁴⁷ Assuming all current signatories ratify the agreement and it comes into force, if an applicant obtains a classical EP, this will still be refracted into a bundle of national patents. However, the UPCt will have jurisdiction for the post-grant life of classical EPs granted in Contracting States which have ratified the AUPC. Moreover, decisions of the UPCt in respect of a challenge raised against such patents will bind all Contracting States to the AUPC.⁴⁸ Only Contracting States not party to the AUPC will retain post-grant jurisdiction for EPs. Therefore, if all current signatories ratify the agreement, the only EU States to retain national jurisdiction under the classical EP route will be non-participating States to the AUPC, namely: Spain, Croatia and Poland. National jurisdiction is also retained for EPC States who are not in the EU who, as noted, cannot join the AUPC.⁴⁹ To complicate matters, there is a seven year transitional period⁵⁰ after the AUPC comes into force during which time patentees who obtain an EP validated in AUPC States can opt-out of the UPP system.⁵¹ To opt out, a patentee must notify the registry and the opt-out will take effect on its entry onto the register.⁵² Once registered, an opt-out means that the UPCt has no jurisdiction over the EP patent bundle and instead, the patents will be subject to relevant national jurisdictions.⁵³

Thus, a complex institutional framework arises whereby EPs are granted by the EPO, and decisions on revocation will be governed either by national courts or the UPCt depending on whether the State is party to the AUPC and during the first seven years depending on whether the patentee has opted-out. Moreover, the UPP needs just the required thirteen ratifications to come into effect. This means that initially it could be an EPUE in thirteen States, increasing to an EPUE in fourteen States etc. depending on when states ratify. This increases the institutional complexity within the system. The diagram below offers a basic overview of the supranational adjudicative bodies responsible for revocation actions under the UPP.

⁴⁷ Art. 3(c)-(d) AUPC include European patents in its scope of application. However, it only applies in respect of EPs granted in Contracting States of the AUPC confirmed by Art. 34 AUPC.

⁴⁸ Art. 38 AUPC.

⁴⁹ The Preamble to the AUPC states: "Considering that this Agreement should be open to accession by any Member States of the European Union, Member States which have decided not to participate in the enhanced cooperation in the area of the creation of unitary patent protection may participate in this Agreement in respect of European patents granted for their respective territory".

⁵⁰ Art. 83 AUPC.

⁵¹ McDonagh 2014, p 9.

⁵² Art. 83(3) AUPC.

⁵³ Preparatory Committee of the Unitary Patent Court 2016.

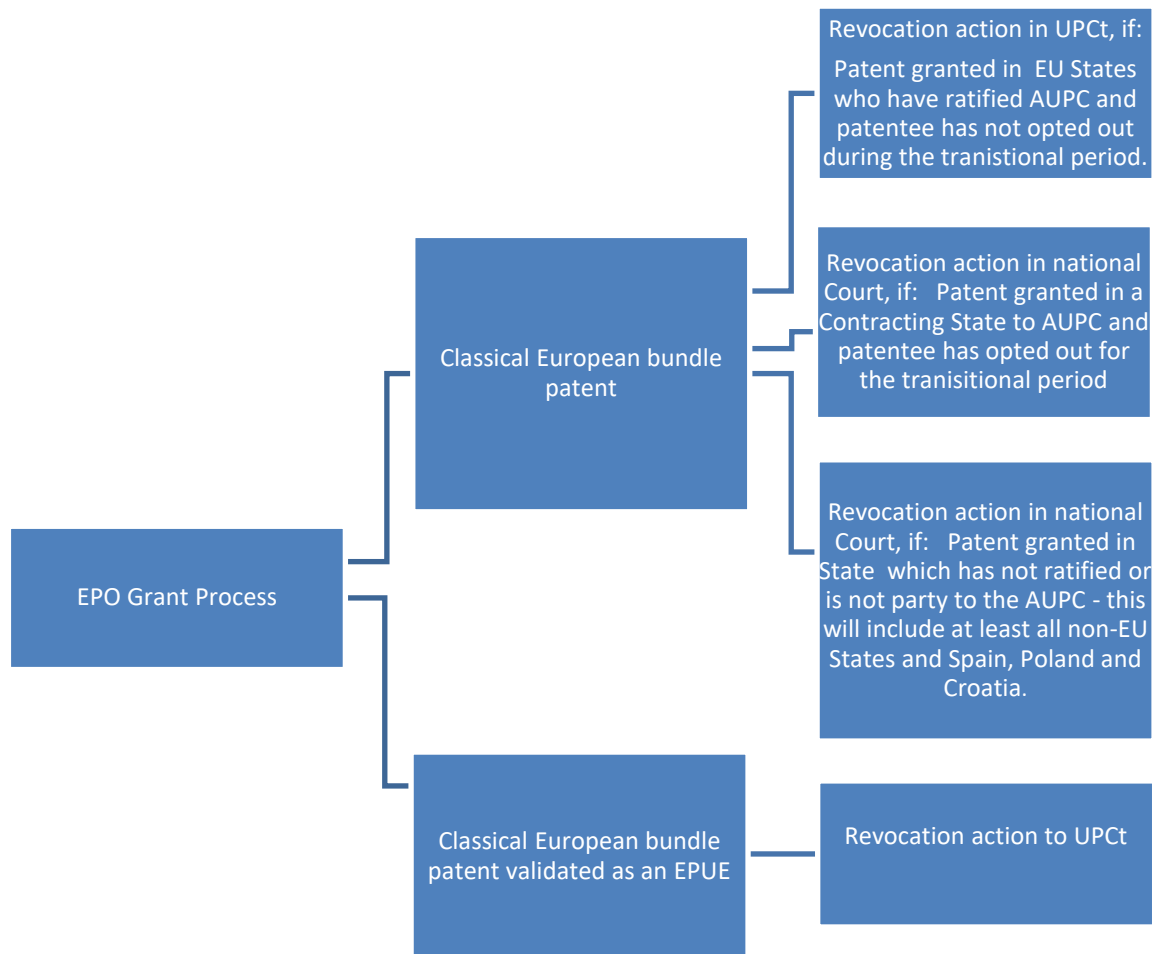


Fig. 1: Decision-making forums for revocation actions following patent grant by the EPO once UPP system is in force.

2.2.2 Opposition Proceedings

Turning to opposition proceedings, under the proposed UPP scheme, the unitary effect of the EPUE created has an ‘accessory’ nature meaning that it: “...*should be deemed not to have arisen to the extent that the basic European patent has been revoked or limited*”⁵⁴. Accordingly, if an EP is successfully challenged through opposition proceedings in the EPO, the EPUE validated as a result will be deemed not to exist. Thus, despite the fact that generally post-grant issues relating to the EPUE are dealt with by the UPCt, opposition proceedings in the EPO will continue to exist. Therefore, at any one time a patent could be challenged on the grounds of the morality provisions through opposition proceedings in the EPO, and also revocation proceedings in the UPCt or national court. The UPCt must be informed of any pending opposition proceedings before the EPO and may decide to stay proceedings if a rapid decision is expected from the EPO.⁵⁵ However, if it does not stay proceedings and upholds

⁵⁴ Recital 7, Regulation 1257/2012, reinforced by Art. 3(2) of the Regulation which states: “It may only be limited, transferred or revoked, or lapse, in respect of all the participating Member States” and Art. 3(3) “The unitary effect of a European patent shall be deemed not to have arisen to the extent that the European patent has been revoked or limited.”

⁵⁵ Art. 33(1) AUPC.

a patent following a challenge, this patent may be subsequently revoked by the EPO. This gives rise to the potential for conflicting interpretations.

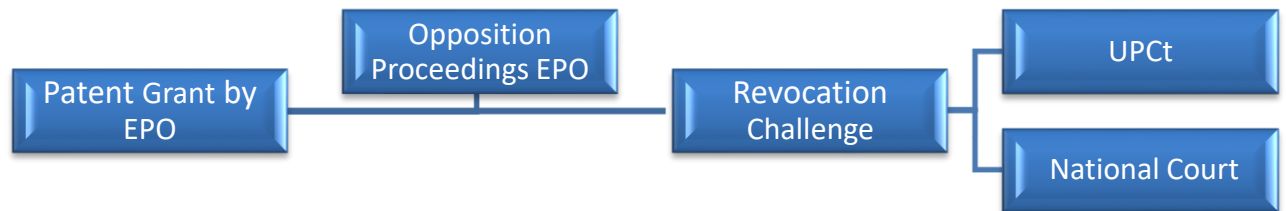


Fig. 2: Simplified representation of the interaction of opposition and revocation proceedings when the UPp comes into effect.

Having said this, the EPO to date has generally taken a light touch approach to the general morality provisions favouring patent grant where possible. Therefore, it is unlikely that this situation would arise. Of more concern in terms of potential divergence is if the EPO dismisses an opposition proceeding and upholds the patent, and a subsequent challenge to the patent through revocation proceedings in the UPCt is accepted. This would create the possibility of conflict as this would render the patent invalid in all AUPC Contracting States, which will be the majority of EU States (subject to all participating States ratifying the agreement) but it would remain valid in non-AUPC States.

2.3 Implications of Institutional Changes for the Morality Provisions

As has been demonstrated, the UPp will significantly alter the adjudicative bodies responsible for revocation proceedings, giving rise to increased institutional overlaps involving three supranational decision-making actors; the Boards of the EPO, UPCt and the CJEU. Moreover, although the UPCt has links to the CJEU and the EPO; however, as will be discussed in part three, this does not mean it will share the CJEU's interpretative approach, and discussions on the UPp suggest a reluctance in involving the CJEU in the UPp system. Thus, the proposed system creates the possibility of further fragmented moral spaces at the supranational level as one will have overlapping areas governed by the UPCt, the CJEU and Boards of the EPO, and these adjudicative bodies may offer differing interpretations of these provisions given their differing institutional contexts.

To illustrate the difficulties which may arise, consider a decision of the UPCt in a revocation action which invalidated an EPUE on the basis of the morality provisions. If rendered invalid by the UPCt, the patent would be invalid in all Contracting States to the AUPC but would remain valid in other States where it was validated as a classical EP. Further national challenges would be required to invalidate these patents. In the absence of such challenges, based on the current planned membership, one would have a patent invalid for 25 of the 38 EPC States but valid in the remaining states. This creates a difficult situation for non-AUPC States if we presume - in light of

the primacy of EU law within the UPCt system and the fact that the EPC is also a source of law for the UPCt - that the UPCt was applying EU law along with the EPC in its decision. If this can be presumed, the denial of a patent by the UPCt in AUPC States would give rise to questions as to its validity in such non-AUPC States. To justify a differing approach, it could be argued that the consensus on morality within AUPC States differed from non-AUPC states. However, it is unlikely that one would have an overwhelming consensus on the morality provisions in twenty five EU States, but not in the remaining non-AUPC States.

To resolve conflicting interpretations, a ruling relating to the UPCt would bind non-participating EU States if the UPCt made a referral to the CJEU whose decision would bind all EU States. Failing this a challenge of the patent in each national court would be necessary to render it invalid in the remaining EU States. Moreover, as there is no binding link from the UPCt or CJEU to the EPOrg, the only means to render such a patent invalid in EPC States who are not in the EU, is through national challenges to the patent grant in each State or opposition proceedings to the EPO. In short, the overlapping supranational layers add considerable complexity to the already multi-layered system leaving open the possibility for conflicting supranational interpretations of the morality provisions. This is problematic due to the overlapping obligations of many States involved to the relevant international agreements evident, namely: the Biotechnology Directive, EPC and AUPC.

3. Institutional Influences on the UPCt in the Application of the Morality Provisions

The proceeding section outlined the deepening supranational fragmentation which the UPP will create and the likely practical issues should conflicting interpretations arise. This section highlights why this is particularly significant in the context of the morality provisions. It argues, that ‘institutions’ such as the EPOrg, and planned UPP system, within which adjudicative bodies are situated give rise to distinctive frameworks wherein adjudicative bodies are subject to differing constraining and predictive influences, and these influences may limit or guide decision-making outcomes. This section commences by outlining a template mapping the main categories of constraining/predictive influences in any institutional framework set out in 3.1; then 3.2 argues why these institutional influences are heightened in the context of the morality provisions; and, finally, 3.3 applies this template of factors to the UPP to analyse the main institutional influences on the UPCt and how these are likely to influence its interpretation of the morality provisions.

3.1 Template for mapping the institutional influences on adjudicative bodies.

Drawing on institutional theories, this article argues that both constraining and predictive influences are evident within all institutional frameworks. Firstly, constraining influences are those which legally constrain a decision-makers’ scope of action and include: (1) the *central objectives* of the overarching institution within which adjudicative bodies sit, and their own statutory objectives. In this vein, Neil MacCormick referred to the importance of having a grasp of the function or main point of an institution as “an explanation of any institution requires an account of the relevant rules set out in light of its point”.⁵⁶ This resonates with the Aristotelian idea

⁵⁶ MacCormick 2007, 36.

of entities of many kinds being accounted for in terms of their final cause⁵⁷ or telos. Such objectives act as constraints on judicial/quasi-judicial bodies as they must act in line with the functions/aims of the institution in which they are situated. This includes the functions and legal competences of the decision-making bodies which curtails its parameters for decision-making. (2) The *path dependencies* of both the overarching institution and the judicial/quasi-judicial body are also significant. Judicial/quasi-judicial decision-makers are *legally constrained* by their past decisions particularly if decisions have already been given on the morality provisions. They are also influenced by past decisions in related areas to which analogies might be drawn given the need for consistency and coherence across a legal framework. Past decisions at a legislative level are also significant as adjudicative bodies must interpret the underlying legal framework by reference to the purpose of the legislation and principles set out within it and related legislation.

Secondly, predictive influences can be discerned within any framework. These are influences which indicate the way a decision-making body may be influenced on a particular question but are not *legally* constraining, an example is: (3) the *structure, role and composition* of judicial/quasi-judicial bodies. Analysing this feature offers insights into how adjudicative bodies can be predicted to act and how external factors might influence decision-making in a particular context as they shape the interpretative community evident.⁵⁸ Finally, of particular relevance is the (4) *inter-institutional influences* exerted on adjudicative bodies which can be either a constraining or predictive influence. In the legal context, this may be a constraining factor if there are hierarchies existing between institutions e.g. the legal obligations the EU would have to the ECHR system should it accede to it. Inter-institutional relationships may also be highly persuasive even if not constraining, e.g. consider the EPOrg's relationship with the ECHR system, where although the EPOrg is not party to the ECHR it arguably will still seek to abide by Convention law given that all of its Contracting States are Convention parties. Analysing inter-institutional relationships therefore offers predictions as to the behaviour of judicial/quasi-judicial decision-making bodies situated within these overarching institutions.

Importantly, this template of factors does not seek to dismiss other influences within an institutional framework nor does it claim to track all influences on decision-making. Rather, it highlights some of the main categories of influences which arise within any institutional framework, and which are significant in the context of the European patent system given many States' overlapping obligations under the EPOrg/EU and now planned UPP system.

3.2 The Morality Provisions: A Heightened Context for Institutional Influence

Such institutional influences are heightened in the context of the morality provisions because of the: (a) the open-ended nature of the legislative provisions and (b) the malleable and subjective nature of morality. Open-textured provisions are those which Hart described as "...a mere legal shell and demand by their express terms to be filled

⁵⁷ Aristotle, *A Treatise on Government* (trans W Ellis) (J M Dent, 1912) 1252b – 1252a: 'For what every being is in its most perfect state, that certainly is the nature of that being, whether it be a man, a horse, or a house: besides, whatsoever produces the final cause and the end which we desire, must be best; but a government complete in itself is that final cause and what is best.' cited in MacCormick 2007, p 36.

⁵⁸ Drahos 1999, pp 441-442.

out with the aid of moral principles...”.⁵⁹ This aptly applies to the morality provisions in the patent system under both the EPC and Biotech Directive as the adjudicative body called upon to interpret these provisions is forced to act as legislator in “formulating the deficit in the legislation”.⁶⁰ This is because aside from the list of four inventions which are expressly excluded from patentability under Art. 6(2) of the Biotechnology Directive, replicated in the relevant Implementing Regulations of the EPC - and these have also required judicial interpretation⁶¹ - there is little by way of guidance⁶² for decision-makers on the scope which the general morality provisions should take or the tests/standards that should be used to assess its application.⁶³ Consequently, adjudicative bodies are left in the unenviable position of having to decipher the parameters these legislative provisions should take. In doing so, decision-makers must act within the legal constraints on them, and are also likely to be cognisant to ensure any decisions taken by them will be accepted by the community which the institution speaks to or serves⁶⁴ which is where predictive influences are of relevance.

Secondly and relatedly, the nature of the morality provisions provides scope for institutional influence as whilst in deciding on the morality of a specific act, we as individuals will arguably internalise the issue and based on our individual values and experiences decide on whether we deem an act moral or not. However, in this context, decision-makers are asked to decide upon the morality of the commercial exploitation of an invention not in their capacity as individual actors, but as representatives of a court/quasi-judicial body which in turn speaks for the overarching institution, i.e. the EU/EPOrg or UPP system. In doing so, decision-makers will consider the decision by internalising it not individually but through the eyes of the sub-institution (the judicial/quasi-judicial body) and in cognisance of the overarching institution in which they are situated: thus an institutionally-subjective application of the morality provisions results. This is supported by Neil MacCormick’s work which argues that legal reasoning on moral dilemmas takes place in a highly institutionalised context.⁶⁵ Seen in this light, the institutional framework evident acts as a prism through which moral questions are considered and filtered in order to reach a decision which is deemed most appropriate for decision-makers representing a particular institution and given the legal constraints on such decision-makers.

In short, adjudicative bodies will give *institutionally tailored* interpretations of open-textured provisions such as the morality provisions. These interpretations will align with the respective purposes/final causes, competences

⁵⁹ Hart 1961, pp 199-200.

⁶⁰ Warren-Jones 2002, p 50.

⁶¹ The EPO was required to consider this provision in Wisconsin Alumni Research Foundation (WARF) (G002/06), Decision of the Enlarged Board of Appeal of 25 November 2008. Whilst, the EU was required to consider it in Case C-34/10 Brüstle v Greenpeace eV [2011] E.C.R. I-9821, and Case C-364/13 International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks, Judgment of the Court, Grand Chamber, 18 December, 2014.

⁶² The main guidance for the EPO is: EPO 2013, para 4.1. However, these do not mention an ethical framework or principles which should be applied for the morality provisions.

⁶³ See Warren Jones 2007, p 832; Warren-Jones 2002, p 59.

⁶⁴ See CW Clayton and DA May, ‘A Political Regimes Approach to the Analysis of Legal Decision’ (1999) Polity 233-252 as reproduced in Peters and Pierre 2007, p 6.

⁶⁵ MacCormick 2009, p 172. MacCormick’s work examined differences between moral reasoning and legal reasoning on moral issues in the judicial context. He argued at p 182 that: “Autonomy in moral judgment means that each person is responsible for her/his view of what is good and bad, right and wrong and can never be overruled on that issue. This is distinct from the issue of what a public agency or authority may be required by law to do in a given dilemma.”.

and characteristics of the institutions within which the decision-making bodies are situated. Taking this view, the institutional framework within which decision-makers act is highly significant for the end outcomes of decision-making. These frameworks are integral to how they refract, internalise and eventually give an interpretation to the morality provisions.

3.3 Institutional Influences on the Morality Provisions under the UPP

The foregoing has demonstrated the significance of institutional influences on the application of open-textured provisions such as the morality provisions. That being the case, it is useful to consider the constraining and predictive influences which may arise in the UPP system and how these are likely to influence the UPCt's interpretation of the morality provisions. Notably, *explicit* path dependencies of the UPCt cannot be considered as it has not come into operation yet so it does not have its own history to influence it. Therefore, the path dependency category will not be examined directly. Nonetheless, it is acknowledged implicit path dependencies are likely in this context; in particular, influences from the EU are likely given that the UPP was an EU proposal and given the UPCt's link with the CJEU and the primacy of EU law under the AUPC. However, as these influences do not stem from the history of the UPCt itself, they will be examined where relevant in the other categories below, and the role of the CJEU will be considered under the *inter-institutional* category.

Applying the template of factors to the UPCt it is demonstrated to be a peculiar body which exists between the current EPOrg and EU systems. It is also a hybrid body in the sense that it is not an EU court *per se*, but has links to the CJEU, however, in characteristics it is more akin to the Boards of the EPO. Therefore, as will be seen, it will provide a distinctive institutional framework for the interpretation of the morality provisions and much is likely to depend on how the relationship between the UPCt and CJEU develops.

3.3.1 Central Objectives of the UPP

In terms of relevant *central objectives* which may influence the UPCt, of particular consequence are the objectives of the EU and the objectives of the statutory framework setting up the UPCt. The objectives of the EU are of relevance because as highlighted the UPP originated as an EU initiative. It was agreed upon by the Council of the European Union and the European Parliament, and solidified with the adoption of two EU regulations. However, the UPCt is not an EU court *per se*; rather it is a court common to the Contracting States of the AUPC and is subject to the same obligations to the EU as national courts.⁶⁶ Nonetheless, EU law has primacy within the UPCt,⁶⁷ and therefore the overarching objectives of the EU would be expected to filter into the UPCt framework. The general EU objectives include the furthering of the internal market within a framework that protects fundamental rights. The EU internal market objectives are reflected in the Preamble to the AUPC which states that:

⁶⁶ Art. 1 AUPC which states: "The Unified Patent Court shall be a court common to the Contracting Member States and thus subject to the same obligations under Union law as any national court of the Contracting Member States."

⁶⁷ Preamble AUPC, Art. 20 AUPC.

“...the cooperation amongst the Member States of the European Union in the field of patents contributes significantly to the integration process in Europe, in particular to the establishment of an internal market within the European Union characterised by the free movement of goods and services and the creation of a system ensuring that competition in the internal market is not distorted.”⁶⁸

The Preamble to the AUPC also refers to the Charter of Fundamental Rights noting that it is part of the sources of law applicable to the UPCt.⁶⁹ However, outside of this reference there is no discussion of the role of human rights or dignity in the application of the AUPC nor are the broader social goals of the EU referred to. This is perhaps unsurprising given that the AUPC deals with all inventions and not just biotechnological inventions and it is in this latter context, that human rights issues have been particularly contentious.⁷⁰ Nonetheless, the absence of references to broader EU goals in the AUPC alongside the repeated references to the harmonisation goals and the fact that the UPCt sits in a somewhat disjointed manner to the EU judicial system, suggests these broader social objectives may not be channelled as directly through the UPCt as they would be within the CJEU.

The objectives set out in Regulation 1257/2012 and the AUPC are also relevant. The primary aim of the Regulation 1257/2012 is stated as being to achieve unitary patent protection in Contracting States,⁷¹ whilst the AUPC seeks to set up one decision-making body for the adjudication of patents within Contracting States in order to reduce fragmentation and achieve this unitary goal. This is affirmed in the Preamble to the AUPC, which highlights the detrimental effects of variation across countries in the patent context. These legislative instruments set out primarily economically framed objectives which prioritise removing fragmentation within the European patent system. If the UPCt perceives as its main function the harmonisation of patent law within a European market, then it may perceive broader social functions narrowly, particularly as no detailed reference to these is alluded to in its statutory instruments.

3.3.2 Composition, Structure of the UPCt

Secondly, turning to the structure and composition of the UPCt, the UPCt is a specialised court⁷² which deals solely with “the settlement of disputes relating to European patents and European patents with unitary effect”.⁷³ In light of this specialised nature, the UPCt may become insulated from broader considerations which generalised courts such as the CJEU adjudicate upon on a daily basis. Instead, the UPCt’s role is more akin to the Boards of the EPO than the CJEU, and similarly to the EPO, judges in it are likely to be unaccustomed to adjudicating upon explicitly moral issues and accordingly may be reluctant to decline patents on this basis, particularly if they are operating within a framework which prioritises harmonisation and the furtherance of the internal market.

This is reinforced when one considers that the UPCt’s judicial members are drawn from within the patent community and may have limited expertise in examining moral issues in other contexts. The UPCt’s eligibility requirements state that judges both legally and technically qualified shall “have proven experience in the field of

⁶⁸ Preamble AUPC.

⁶⁹ Ibid.

⁷⁰ See, Case C-34/10 *Brüstle v Greenpeace eV* [2011] E.C.R. I-9821.

⁷¹ Recital 26, Regulation 1257/2012.

⁷² A court whose jurisdiction can be described in terms of the subject matter it deals with rather than geographical factors, see: Petersen, Riis and Schovsbo 2015 which cites Gugliuzza, 2012, p. 1445.

⁷³ Art. 1 AUPC.

patent litigation”.⁷⁴ Legally-qualified members must “possess the qualifications for appointment to judicial offices in a Contracting Member State”⁷⁵ whilst technically qualified members must have a degree, proven expertise in a field of technology, and knowledge of civil law and procedure relevant to patent litigation.⁷⁶ The training framework for the judiciary⁷⁷ aims to “improve and increase available patent litigation expertise and to ensure broad geographic distribution of such specific knowledge and experience”.⁷⁸ However, there is no reference to training on broader aspects of law or ethics. This fact that ethics/rights are not referred to in the AUPC in relation to training reinforces the likely marginalisation of such issues.

Indeed, Petersen, Riis and Schovsbo have highlighted the main risk of specialisation is that the UPCt may develop: “...certain biases that lead the court to downplay or even disregard issues of a general societal nature unrelated to the technical issues of patent law.”⁷⁹ In light of the objectives of the UPP, they argue that a bias may result which favours achieving agreement and avoiding diversity.⁸⁰ Moreover, they argue that specialised courts have been recognised as being more likely to follow or identify with the objectives and statutory scheme they are administering and may identify too strongly with their litigants.⁸¹ Accordingly, such judicial members may “develop a tunnel vision and become overly sympathetic to policies furthered by the law that they administer or who are overly sympathetic to “capture” by the bar that regularly practices before them.”⁸² Institutional theories support and reinforce these points and considered together these arguments, suggest that the UPCt may focus closely on the objectives set out in its statutory scheme setting up the UPCt and in doing so may seek to preserve a narrow interpretation of the morality provisions.

3.3.3 Inter-Institutional Influences: The UPCt and the CJEU: A Bridge over Troubled Waters?

In terms of inter-institutional influences and how these may influence the application of the morality provisions, a crucial factor, is the UPCt’s relationship with the CJEU. This distinguishes it from the EPO and depending on how this relationship develops it could offer a potential bridge to mediate differences between the EPOrg and EU. In this context, the UPCt may make requests for preliminary rulings to the CJEU to ensure the consistent and uniform application of EU law.⁸³ Referrals can be made by the CFI or Court of Appeal in the UPCt and in such cases, there will be a stay on the proceedings⁸⁴ until the CJEU has delivered its opinion.

⁷⁴ Art. 15 AUPC. See: Thornham, and Küppers 2014, pp 57-59.

⁷⁵ Art. 15(2) AUPC.

⁷⁶ Art. 15(3) AUPC. See also, Art. 2(3) Statute of the UPCt. This states: “Experience with patent litigation which has to be proven for the appointment pursuant to Article 15(1) of the Agreement may be acquired by training under Article 11(4)(a) of this Statute.”

⁷⁷ Art. 19 AUPC.

⁷⁸ Ibid.

⁷⁹ Petersen, Riis and Schovsbo, 2015.

⁸⁰ Ibid.

⁸¹ Ibid citing Posner 1985, pp 150-157; Guidliuzza 2012, p 1149; Dreyfuss 1989.

⁸² Petersen, Riis and Schovsbo 2015.

⁸³ Art. 21 AUPC.

⁸⁴ Ibid.

However, some commentators have expressed reluctance for patent law to come under the influence of the CJEU in this way.⁸⁵ One of the main objections to the CJEU's role in this area is on the grounds that it is a generalist court whose judiciary do not have the required expertise and knowledge of patent law. This is deemed to be problematic given the specialist and technical nature of patent law and questions have been raised in relation to the quality of judgments the CJEU would deliver.⁸⁶ Other concerns include the potential for the CJEU's involvement to cause delay and increase the costs of proceedings.⁸⁷ Indeed, there are limited substantive legal provisions in the AUPC which in itself limits the CJEU role. However, unlike other areas of patent law where there are no EU legislation applicable, the Biotechnology Directive provides a number of substantive provisions on patent law including the morality provisions. Therefore, decisions of the UPCt concerning the meaning of the morality provisions under Art. 6 of this Directive fall directly within the remit of the CJEU.

The UPCt has significant responsibility in this context because once it becomes operational, it will not be different national courts referring matters; rather it will be the UPCt which will decide exclusively on such issues⁸⁸ for EPUEs and EPs granted in EU States party to the AUPC. However, if reluctance is already being expressed around the CJEU's role, this suggests the UPCt may only make limited reference to the CJEU in future. This reluctance to involve the CJEU appears to stem from a mistrust of the CJEU in the 'technical' field of patent law. This aligns with a view of the patent law as insulated or fenced off from the broader legal and ethical issues.⁸⁹ Contrary to this view, whilst acknowledging the need for scientific expertise in examining technical issues relating to patent applications, this article argues that the application of the morality provisions is an area which explicitly involves broader social issues and would benefit from the input of a generalist court like the CJEU. This is particularly true if, as recent case law suggests, the morality provisions are to incorporate human rights considerations more broadly.⁹⁰

In short, a balance is needed on the CJEU's involvement depending on the issues raised: broader social issues or those involving human rights may require oversight from the CJEU, whilst technical, scientific questions should generally be resolved by the specialist UPCt.⁹¹ However, it is crucial that patent law is not viewed as solely a technical/scientific endeavour. The grant of a patent and patent law generally may give rise to fundamental questions of rights and/or important social questions particularly in relation to biotechnological inventions. Indeed, the Biotechnology Directive makes express reference the protection of fundamental rights and to the need for patent law to be applied in a way which safeguards human dignity.⁹² It is thus vital that some oversight from the CJEU is embraced.

⁸⁵ For a discussion see, Brikhof, and Ohly 2013, p 215; Jacob 2011, p 3.

⁸⁶ Brikhof, and Ohly 2013, p 215.

⁸⁷ Ibid.

⁸⁸ Ibid, p 216.

⁸⁹ Bently and Sherman 1995.

⁹⁰ Case C-34/10 *Brüstle v Greenpeace eV*, Judgment of the Court (Grand Chamber), 18th October, 2011, [2011] E.C.R. I-9821; Case T0149/11 of 24 January 2013: Method and device for processing a slaughtered animal or part thereof in a slaughterhouse.

⁹¹ Brikhof and Ohly 2013, p 216, who have argued that: "...issues which concern fundamental freedoms, human rights, or the balance between patent protection and countervailing interests reach the CJEU, while practical issues of patent law will be decided by specialist judges."

⁹² Recital 16 and 43, Biotech Directive

To achieve this balance the UPCt will need to show openness to referring questions to the CJEU on such issues. This could also help mediate tensions as even though the UPCt is not responsible for all EU States, an interpretation by the CJEU of the morality provisions in the Biotechnology Directive would bind other EU States. Furthermore, if the UPCt became closely aligned with the CJEU on such issues it would also be useful as the UPCt has the ability to provide an indirect judicial check on the EPO in its application of the morality provisions. Currently, following patent grant by the EPO, aside from a referral to the CJEU which denies a patent and is applicable in all EU States, a patent needs to be challenged individually in each EPC State to render it invalid. In contrast, the UPCt system offers a single track to invalidation in participating States should a revocation action before the UPCt succeed as UPCt decisions have automatic effect in all AUPC States. Hence the denial of a patent by the UPCt would place pressure on the EPO to conform to the UPCt approach; as to do otherwise could jeopardise the EPO's patent grant role. Thus, the UPCt could help forge a process of soft harmonisation at an adjudicative level between the EPOrg and EU.⁹³

3.3.4 Reflection on Institutional Influences in the UPP

Whilst the UPP raises many questions at an institutional level, however, if it involved the CJEU in decisions, it has the potential to introduce an indirect judicial check on the EPO in the grant of patents, and to act as a bridge between the EPOrg and EU in this context. Having said this, if it adjudicates on the morality provisions with limited input from the CJEU, its institutional characteristics as examined above suggest that it will be institutionally predisposed to apply the morality provisions in a manner which may not necessarily align with broader EU goals or aims in the Biotechnology Directive. Indeed, it is not at all clear whether the UPCt itself is institutionally structured to deliver on the goals of the Biotechnology Directive in its interpretation of the morality provisions which may give rise to questions surrounding the defensibility of these provisions.

4. The Morality Provisions and the 'Unitary' nature of the EPUE

Aside from these core institutional issues, also relevant to the application of the morality provisions is the unitary nature of EPUE. Recital 7 to the Regulation states that:

“The main feature of a European patent should be its unitary character, i.e. providing *uniform protection* and having *equal effect in all the participating Member States*. Consequently, a European patent with unitary effect should *only be limited, transferred or revoked, or lapse, in respect of all the participating Member States ...*” [Emphasis added]

In other words, the EPUE will either stand or fall as a whole and cannot be revoked or limited in respect of particular Contracting States which may object. The UPCt could still arguably allow for divergence in respect of classical EPs which will fall under its jurisdiction and are not EPUEs as there is no unitary clause attaching to

⁹³ Petersen, Riis and Schovsbo 2015. They argue it could have a watchdog role on decisions of the EPO.

these patents. However, there does not appear to be any means to accommodate divergence amongst States in respect of EPUEs. Moreover, it can be inferred from the recital above that an EPUE cannot be converted back to a classical EP bundle if the patent is subsequently objected to on the basis of moral concerns in a particular Contracting State after registration as an EPUE. Indeed, any other interpretation of this recital would render its wording unnecessary. Instead, the recital is clear that EPUEs can only be limited, revoked or lapsed in *all* Contracting States.

This uniformity is problematic for the morality provisions as moral questions may give rise to divergent and entrenched views which can vary widely amongst States in light of differing historical and cultural traditions. Moreover, the EU's legal framework guarantees protection for such traditions: Art 3(3) TEU provides protection for cultural and linguistic diversity of its States, whilst Art. 4(2) TEU provides protection for States' national identities. Moral objections to the commercialisation of a particular biotechnological invention may be rooted in moral traditions or beliefs and thus, would be covered by these protections. Therefore, under EU law some mechanism for providing for national divergence on the morality provisions is necessary.

Moreover, the ECHR, which all States party to the EPC are also signatories of, provides space for Contracting States to diverge on issues where there is no consensus such as moral questions. As noted, the ECtHR generally provides a 'margin of appreciation' i.e. discretion or scope for manoeuvre bestowed upon ECHR States in fulfilling their obligations under the Convention.⁹⁴ The rationale for this doctrine was set out in, *Handyside v United Kingdom*⁹⁵ where the ECtHR stated that it is the role of each State, in the first place, to secure the rights and liberties enshrined in the Convention as the "machinery of protection established by the Convention is subsidiary to the national systems safeguarding human rights."⁹⁶ Referring to Art. 10(2) it stated that "...[it] is not possible to find in the domestic law of the various contracting states a uniform European conception of morals,"⁹⁷ and views taken by Contracting States on the requirements of morals may vary from time to time and place. Instead, it stated that:

"By reason of their direct and continuous contact with the vital forces of their countries, State authorities are in principle in a better position than the international judge to give an opinion on the exact content of these requirements..."⁹⁸

Hence, both the EU and the ECHR systems generally provide deference to States on moral issues. Furthermore, the need for deference on the morality provision in Art 6(1) of the Biotechnology Directive was expressly confirmed by the CJEU in the *Netherlands* decision,⁹⁹ which stated that courts of the Member States have "a *wide scope for manoeuvre* in applying this exclusion."¹⁰⁰ This CJEU offered as a rationale for this the need:

⁹⁴ Yourow 1996, p 13.

⁹⁵ *Handyside* European Court of Human Rights, Series A/24, 1976.

⁹⁶ *Ibid*, para. 48

⁹⁷ *Ibid*.

⁹⁸ *Ibid*.

⁹⁹ Case 377/98 *Netherlands v European Parliament and Council* [2001] ECR I-07079.

¹⁰⁰ *Ibid*, para. 37

“to take account of *the particular difficulties to which the use of certain patents may give rise in the social and cultural context of each Member State*, a context which the national legislative, administrative and court authorities are better placed to understand than are the Community authorities.”¹⁰¹

This reasoning is almost identical to the ECtHR’s reasoning for the margin of appreciation doctrine. Moreover, deference for States on these provisions is further supported by reference to the wording of the recital 39 of the Biotechnology Directive which states that:

“Whereas ordre public and morality correspond in particular to ethical or moral principles recognised *in a Member State*, respect for which is particularly important in the field of biotechnology...” [Emphasis added]

The use of MS in the singular suggests that the principle was envisaged as being assessed on a national level¹⁰² to accommodate national differences in terms of the morality clause as it applies to patents. There is scope in the classical EP route for national divergence post-grant through revocation proceedings discussed above¹⁰³ which could be used to accommodate objections of individual States on the basis of the morality provisions.¹⁰⁴ This mechanism for allowing divergence at the post-grant stage will be absent for EPUEs and is deeply problematic for these stated reasons.

To resolve these issues, one solution would be that the UPCt would seek opinions of national courts in each of the Contracting States when revocation challenges based on morality provisions are raised.¹⁰⁵ If individual States object the EPUE should lose unitary effect and be converted back to a classical EP bundle of patents. Patents could then be revoked in States who object on the basis of morality provisions, but would remain valid in other States, albeit without unitary effect. This could be used to accommodate a margin of discretion for States given the sensitive moral issues at stake and the CJEU’s policy of allowing some manoeuvre on such issues. It would require a change to the AUPC explicitly providing for this route in cases of objections on the basis of the morality provisions.

4.1 Morality Provisions under the UPP: Whose morality?

Finally, another issue posed by the unitary nature of the EPUC is which territory the UPCt would judge the moral stance in should a patent be challenged. In particular, if it is to take a unitary position, it is not clear if the UPCt will seek to ascertain consensus in the current twenty five AUPC Contracting States, the twenty eight EU States or the thirty eight EPC States in deciding whether an invention should be excluded based on the morality provisions. The UPCt will need to either adopt a lowest common denominator approach granting a patent unless deemed abhorrent and consensus on this was held by all States, or a maximalist approach which would prohibit patents if any State objected.

¹⁰¹ Ibid, para. 38

¹⁰² Bonadio 2012, p 439.

¹⁰³ Plomer 2006.

¹⁰⁴ Ibid 133.

¹⁰⁵ This solution has previously been proposed and advocated for in the context of the application of the morality provisions in the EPO system by Torremans 2009, pp 300-301.

An added complication is Art. 7 of the Regulation 1257/361, which states that:

“A European patent with unitary effect *as an object of property* shall be treated in its entirety and in all the participating Member States as a national patent of the participating Member State in which that patent has unitary effect”. [Emphasis added]

This provision applies in relation to the treatment of patent law where there is no substantive law¹⁰⁶ within the AUPC, Biotechnology Directive or EPC governing an area and applies specifically to the property aspects of patents, namely, to transfer, licensing, encumbrance, enforcement and other aspects where the legal ownership of patents is in issue.¹⁰⁷ On this basis, it may be a stretch to suggest that this would apply to the UP Ct’s application of the morality provisions. Nonetheless, whilst there is an applicable legislative provision for the morality provisions in both the EPC and Biotechnology Directive, however, it is not clear whose standard of morality should apply which is not specified in the legislation. Moreover, a property right is in issue, as morality provisions can be invoked to challenge a patent via revocation proceedings which relates to the removal of a patent and therefore arguably property rights. Hence, an argument could be made that Art. 7 would apply in this context.

If Art. 7 did apply it would mean that the UP Ct must adjudicate any actions on the basis of the national law in one Contracting State. In terms of the applicable national law, this will be the law of the State where the applicant had his/her residence or principal place of business on the date of filing the application for a European patent, or if not applicable, where the applicant had a place of business at the date of filing. If neither of these apply, then the EPUE shall be treated as a national patent of the State where the EPOrg has its headquarters i.e. Munich, and treated according to German law.¹⁰⁸ Also of relevance is Art. 5(2) which as discussed states that the unitary patent right and limitations shall be uniform to all participating States. Kaisi argues that taken together, Art. 5(2) and Art. 7 does not mean the unitary patents must be interpreted in a uniform way in all cases involved rather a particular EPUE must be treated in a uniform way and must be interpreted according to the national law of one State for the entire territory of the enhanced co-operation.¹⁰⁹ It has been questioned whether this complies with Art. 118 of the TFEU¹¹⁰ as it fails to provide for uniformity between patents in respect of the property aspect. In the context of the morality provisions the reference to “Member State” in the singular in recital 39 of the Biotechnology Directive, noted above, is significant as whilst the provision to date had been interpreted as giving discretion to MSs should they wish to deny patents, it is questionable whether Art. 7 applied in this context could be used to support the view that the law of one State should apply in this manner.

If this provision applied to the morality provisions it would mean that the UP Ct would be required to judge the challenge by reference to the law of one State. This would apply the moral tradition of one State in all States, thereby bringing the moral tradition of one State would be brought to bear on all MSs. This would be contrary to

¹⁰⁶ Brikhof, and Ohly 2013, p 212.

¹⁰⁷ Mullerstoy and Paschold, 2014. This is discussed in: Ullrich 2012c, pp 1-17.

¹⁰⁸ Art. 7(3) AUPC.

¹⁰⁹ Kaisi 2014, p 179.

¹¹⁰ Ibid 179. See also Ullrich 2012c.

EU responsibilities to protect MS's moral traditions¹¹¹ and also contrary to obligations under the ECHR. Article 6(2) of the Biotechnology Directive, detailing the specific morality provisions is not in issue in this context as it has previously been accepted that this provision must be interpreted in a uniform manner in all EU States. However, it would be deeply problematic if applied to Art 6(1) of the Biotechnology Directive as it would lead to the UPCt having to enforce a uniform interpretation in all States using the standard of one State as a baseline. It could also engender uncertainty and forum shopping where States perceived as having strict moral traditions could be avoided in patent disputes by changing one's place of business.

5. Conclusion

A unitary patent system was expected to offer a more institutionally sound basis for assessing the morality provisions than provided under the classical EP route.¹¹² However, the UPP as it currently stands gives rise to deeper institutional questions for these provisions. The EPO remains the granting body and therefore none of the existing institutional questions have been addressed. Moreover, at post-grant stage, the UPP results in further fragmentation of the European patent system by adding the UPCt and increasing many States obligations to differing international instruments. This is practically problematic as at the most basic level even discerning who has jurisdiction over classical EPs will be difficult particularly during the transitional period when applicants may opt-out of the UPP system. More troubling, is that under the UPP and the morality provisions will be applied by three supranational decision-making bodies, which as demonstrated in part three are situated in differing institutional contexts and thus are not configured to apply these provisions in the same manner. If these bodies give interpretations denying patents on the basis of the morality provisions in all of their Contracting States, this could give rise to conflicting interpretations which is problematic given States overlapping obligations to differing international treaties.

One means to ameliorate tensions in this context is for the UPCt to develop strong links with the CJEU in the interpretation of morality provisions. This article has argued that these provisions are an example of an instance where the CJEU's generalist perspective is deeply warranted. Contrary to views which have argued in favour of limiting the role of the CJEU in the UPP system, this article argues that it is vital for the UPCt to refer cases involving issues of substantive EU law which gives rise to broader social or rights questions to the CJEU should the need arise. In taking this view, the article acknowledges the need for specialist expertise on technical/scientific issues that arise in patent law, however, social issues are also deeply implicated in the patent context and we must ensure the UPCt does not become a vehicle to insulate patent law from such broader concerns. Moreover, if the UPCt developed links with the CJEU in the context of the morality provisions thereby aligning itself closer to the CJEU, its functions could be used to act as a check on the role of the EPO, as decisions of the UPCt bind all AUPC States and CJEU decisions (should the UPCt refer a question to it) would bind all EU States. This in turn would have persuasive influence on the EPO given that EU and AUPC States would make up a large proportion of the EPO's thirty eight States. This would allow a means to achieve soft harmonisation between EPO and CJEU practices, which may be necessary in some cases given the institutional influences these bodies are subject to. The

¹¹¹ Kaisi 2014, p 179.

¹¹² Plomer 2009.

article has also demonstrated that a reluctance by the UP Ct to involve the CJEU in the application of the morality provisions would cause difficulties as it is not clear that the UP Ct, is institutionally configured to deliver similar interpretations/reasoning on the morality provisions as the CJEU would give should the case arise.

Another issue which must be revisited in the context of the morality provisions is the ‘unitary’ nature of the EPUE. This does not provide any means for States to diverge on moral issues in this context. This is contrary to EU and ECHR obligations to respect national traditions and identities. It is also contrary to the Biotechnology Directive and to the CJEU’s decision in the *Netherlands* case which confirmed a scope of manoeuvre for national States on the morality provisions. Instances of States refusing patents on moral issues are likely to be rare occurrences but they are nonetheless significant, and should be accommodated. In order to do so, the article proposes a system of obtaining opinions from national courts on the morality provisions should a challenge arise. If States wish to deny patents on this basis, there should be a means to convert the EPUE back into a classical EP bundle to respect such views and also allow it to be valid in other States. This would also address the question over whether morality should be adjudicated at a national, AUPC State, EU or EPC State level in such context, as each national State view would be accounted for.

More generally, this article has demonstrated, the significance of institutional frameworks for the interpretation of open-textured provisions such as the morality provisions. It set out a novel template in part 3, applied here to the UP Ct, but which can be used in other contexts to examine such issues where overlapping State obligations to multiple international instruments arise. Crucially, it has argued that ‘institutions’ are vital factors and forces in the examination of decision-making and this needs to be firmly recognised and embedded into discussions on the establishment of new courts, such as the UP Ct.

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